



4160-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2013-N-0823]

Agency Information Collection Activities: Proposed Collection; Comment Request; Format and Content Requirements for Over-the-Counter Drug Product Labeling

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. Under the Paperwork Reduction Act of 1995 (the PRA), Federal Agencies are required to publish notice in the Federal Register concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on the standardized format and content requirements for the labeling of over-the-counter (OTC) drug products.

DATES: Submit either electronic or written comments on the collection of information by [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

ADDRESSES: Submit electronic comments on the collection of information to <http://www.regulations.gov>. Submit written comments on the collection of information to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Ila S. Mizrachi, Office of Information Management, Food and Drug Administration, 1350 Piccard Dr., PI50-400B, Rockville, MD 20850, 301-796-7726, Ila.Mizrachi@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501-3520), Federal Agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. “Collection of information” is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes Agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal Agencies to provide a 60-day notice in the Federal Register concerning each proposed collection of information, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) Whether the proposed collection of information is necessary for the proper performance of FDA’s functions, including whether the information will have practical utility; (2) the accuracy of FDA’s estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Format and Content Requirements for OTC Drug Product Labeling--(OMB Control Number
0910-0340)--Extension

In the Federal Register of March 17, 1999 (64 FR 13254) (the 1999 labeling final rule), we amended our regulations governing requirements for human drug products to establish standardized format and content requirements for the labeling of all marketed OTC drug products in part 201 (21 CFR Part 201). The regulations in part 201 require OTC drug product labeling to include uniform headings and subheadings, presented in a standardized order, with minimum standards for type size and other graphical features. Specifically, the 1999 labeling final rule added new § 201.66 to part 201. Section 201.66 sets content and format requirements for the Drug Facts portion of labels on OTC drug products.

On June 20, 2000 (65 FR 38191), we published a Federal Register final rule that required all OTC drug products marketed under the OTC monograph system to comply with the labeling requirements in § 201.66 by May 16, 2005, or sooner (65 FR 38191 at 38193). Currently marketed OTC drug products are already required to be in compliance with these labeling requirements, and thus will incur no further burden to comply with Drug Facts labeling requirements in § 201.66. Modifications of labeling already required to be in Drug Facts format are usual and customary as part of routine redesign practice, and thus do not create additional burden within the meaning of the PRA. Therefore, the burden to comply with the labeling requirements in § 201.66 is a one-time burden applicable only to new OTC drug products introduced to the marketplace under new drug applications (NDAs), abbreviated new drug applications (ANDAs), or an OTC drug monograph, except for products in "convenience size" packages.¹ New OTC drug products must comply with the labeling requirements in § 201.66 as

¹ In a final rule published in the Federal Register of April 5, 2002 (67 FR 16304), the Agency delayed the

they are introduced to the marketplace.

Based on a March 1, 2010, estimate provided by the Consumer Healthcare Products Association (75 FR 49495 at 49496), we estimated that approximately 900 new OTC drug product stock keeping units (SKUs) are introduced to the marketplace each year. We estimated that these SKUs are marketed by 300 manufacturers. We estimated that the preparation of labeling for new OTC drug products would require 12 hours to prepare, complete, and review prior to submitting the new labeling to us. Based on this estimate, the annual reporting burden for this type of labeling is approximately 10,800 hours.

OTC sunscreen products were previously not included in our consideration of the burden to comply with the Drug Facts labeling requirements in § 201.66. We specifically exempted OTC sunscreen products from complying with the 1999 labeling final rule until we lifted the stay of the sunscreen final rule published in the Federal Register of May 21, 1999 (64 FR 27666). In the Federal Register of December 31, 2001 (66 FR 67485), we stayed the 1999 sunscreen final rule indefinitely. Additionally, in the Federal Register of September 3, 2004 (69 FR 53801), we delayed the § 201.66 labeling implementation date for OTC sunscreen products indefinitely, pending future rulemaking to amend the substance of labeling for these products. In the Federal Register of August 27, 2007 (72 FR 49070), we proposed changes to labeling and related testing requirements for sunscreen products to address both ultraviolet A and ultraviolet B radiation, and we anticipated that sunscreen products would become subject to § 201.66 at the time any resultant final rule becomes effective. In the Federal Register of June 17, 2011 (76 FR 35620),

compliance dates for the 1999 labeling final rule for all OTC drug products that: (1) Contain no more than two doses of an OTC drug; and (2) because of their limited available labeling space, would require more than 60 percent of the total surface area available to bear labeling to meet the requirements set forth in § 201.66(d)(1) and (d)(9) and, therefore, qualify for the labeling modifications currently set forth in § 201.66(d)(10) (67 FR 16304 at 16306). The Agency issued this delay in order to develop additional rulemaking for these "convenience size" products (December 12, 2006; 71 FR 74474). These products are not currently subject to the requirements of § 201.66. PRA approval for

we published a final rule that established testing and labeling requirements for OTC sunscreen products. This 2011 final rule lifted the delay of the § 201.66 labeling implementation date for OTC sunscreen product. The compliance dates for the 2011 final rule were June 18, 2012, for sunscreen products with annual sales of \$25,000 or more and June 17, 2013, for sunscreen products with annual sales of less than \$25,000, but we later delayed these compliance dates to December 17, 2012, and December 17, 2013, respectively, when we published an extension date notice on May 11, 2012 (77 FR 27591).

All currently marketed sunscreen products are, therefore, already required to be in compliance with the Drug Facts labeling requirements in §201.66 , and thus will incur no further burden under the information collection provisions in the 1999 labeling final rule. However, a new OTC sunscreen drug product, like any new OTC drug product, will be subject to a one-time burden to comply with Drug Facts labeling requirements in § 201.66. We estimated that 60 new SKUs of OTC sunscreen drug products would be marketed each year (77 FR 27234). We estimated that these 60 SKUs would be marketed by 30 manufacturers. We estimated that approximately 12 hours would be spent on each label, based on the most recent estimate used for other OTC drug products to comply with the 1999 Drug Facts labeling final rule, including public comments received on this estimate in 2010 that addressed sunscreens.

In determining the burden for § 201.66, it is also important to consider exemptions or deferrals of the regulation allowed products under § 201.66(e). Since publication of the 1999 labeling final rule, we have received only one request for exemption or deferral. One response over an 8-year period equates to an annual frequency of response equal to 0.125. In the 1999 labeling final rule, we estimated that a request for deferral or exemption would require 24 hours

any requirements to which they may be subject in the future will be handled in a separate rulemaking.

to complete (64 FR 13254 at 13276). We continue to estimate that this type of response will require approximately 24 hours. Multiplying the annual frequency of response (0.125) by the number of hour per response (24) gives a total response time for requesting exemption or deferral equal to 3 hours.

FDA estimates the current burden of this collection of information as follows:

Table 1.--Estimated Annual Third-Party Disclosure Burden¹

21 CFR Section	No. of Respondents	No. of Disclosures per Respondent	Total Annual Disclosures	Average Burden per Disclosure	Total Hours
201.66(c) and (d) for new OTC drug products	300	3	900	12	10,800
201.66(c) and (d) for new OTC sunscreen products	20	3	60	12	720
201.66(e)	1	0.125	0.125	24	3
Total					11,523

¹There are no capital costs or operating and maintenance costs associated with this collection of information.

Dated: July 16, 2013.

Leslie Kux,

Assistant Commissioner for Policy.